CLAIMS:

1. A diagnostic method comprising obtaining a population of patient-derived acquired immunodeficiency virus and quantitating the proportion of virus using the CXCR4 and/or CCR5 coreceptor.

5   2. The diagnostic method according to claim 1, wherein the acquired immunodeficiency virus is selected from the group consisting of HIV-1 and HIV-2.

3. The method according to claim 1, wherein quantitating the proportion of virus using the CXCR4 and CCR5 coreceptor comprises determining the ratio of virus using the CXCR4 coreceptor compared to virus using the CCR5 coreceptor.

10   4. A diagnostic method comprising the steps of:

    1) obtaining patient-derived acquired immunodeficiency virus;

    2) deriving biological clones therefrom;

    3) assaying the clones for CXCR4 coreceptor use;

    4) assaying the clones for CCR5 coreceptor use; and

15   5) determining the ratio of virus using the CXCR4 coreceptor compared to virus using the CCR5 coreceptor.

5. The diagnostic method according to claim 4, wherein the acquired immunodeficiency virus is selected from the group consisting of HIV-1 and HIV-2.

6. A diagnostic method comprising obtaining patient-derived acquired
20   immunodeficiency virus and assaying the virus for coreceptor use before initiating antiretroviral therapy to determine a suitable antiretroviral treatment regimen.

7. The diagnostic method according to claim 6, wherein the acquired immunodeficiency virus is selected from the group consisting of HIV-1 and HIV-2.

8. The diagnostic method according to claim 6, wherein the antiretroviral therapy is selected from the group consisting of highly active antiretroviral therapy (HAART), protease inhibitors, fusion inhibitors, integrase inhibitors, coreceptor specific agents, 3TC, AZT, nevirapine, non-nucleoside analogue reverse transcriptase inhibitors and nucleoside analogue reverse transcriptase inhibitors.

9. A diagnostic method comprising obtaining patient-derived acquired immunodeficiency virus and assaying the virus for coreceptor use after initiating antiretroviral therapy to monitor efficacy of an antiretroviral treatment regimen and where efficacy of the treatment is directly related to decrease of CXCR4 coreceptor use.

10. The diagnostic method according to claim 9, wherein the acquired immunodeficiency virus is selected from the group consisting of HIV-1 and HIV-2.

11. The diagnostic method according to claim 9, wherein the antiretroviral therapy is selected from the group consisting of highly active antiretroviral therapy (HAART), protease inhibitors, fusion inhibitors, integrase inhibitors, coreceptor specific agents, 3TC, AZT, nevirapine, non-nucleoside analogue reverse transcriptase inhibitors and nucleoside analogue reverse transcriptase inhibitors.

12. A diagnostic method comprising the steps of:

    1) obtaining patient-derived acquired immunodeficiency virus;

    2) deriving biological clones therefrom;

    3) assaying the clones for CXCR4 coreceptor use;

    4) assaying the clones for CCR5 use; and

    5) determining the ratio of virus using the CXCR4 coreceptor compared to virus using the CCR5 coreceptor,

before initiating antiretroviral therapy to determine a suitable antiretroviral treatment regimen.

13. The diagnostic method according to claim 12, wherein the acquired immunodeficiency virus is selected from the group consisting of HIV-1 and HIV-2.

14. The diagnostic method according to claim 12, wherein the antiretroviral therapy is selected from the group consisting of highly active antiretroviral therapy (HAART), protease inhibitors, fusion inhibitors, integrase inhibitors, coreceptor specific agents, 3TC, AZT, nevirapine, non-nucleoside analogue reverse transcriptase inhibitors and nucleoside analogue reverse transcriptase inhibitors.

15. A diagnostic method comprising the steps of:

1) obtaining patient-derived acquired immunodeficiency virus;

2) deriving biological clones therefrom;

3) assaying the clones for CXCR4 coreceptor use;

4) assaying the clones for CCR5 use; and

5) determining the ratio of virus using the CXCR4 coreceptor compared to virus using the CCR5 coreceptor

after initiating antiretroviral therapy to monitor efficacy of a antiretroviral treatment regimen and where efficacy of the treatment is directly related to decrease of CXCR4 coreceptor use.

16. The diagnostic method according to claim 15, wherein the acquired immunodeficiency virus is selected from the group consisting of HIV-1 and HIV-2.

17. The diagnostic method according to claim 15, wherein the antiretroviral therapy is selected from the group consisting of highly active antiretroviral therapy (HAART), protease inhibitors, fusion inhibitors, integrase inhibitors, coreceptor

specific agents, 3TC, AZT, nevirapine, non-nucleoside analogue reverse transcriptase inhibitors and nucleoside analogue reverse transcriptase inhibitors.

18. A diagnostic composition comprising an indicator cell line attached to a solid support comprising a micro-chip.

5 19. A composition according to claim 17, in the form of a kit; and, the kit optionally contains instructions for employing the indicator cell line in a diagnostic method.

20. A diagnostic method comprising determining the sequence of an acquired immunodeficiency virus envelope gene V3 region before initiating antiretroviral therapy to determine a suitable antiretroviral treatment regimen.

10 21. The diagnostic method according to claim 20, wherein the envelope gene encodes gp160 or gp120.

22. The diagnostic method according to claim 20, wherein the acquired immunodeficiency virus is selected from the group consisting of HIV-1 and HIV-2.

23. The diagnostic method according to claim 20, wherein the antiretroviral therapy is
15 selected from the group consisting of highly active antiretroviral therapy (HAART), protease inhibitors, fusion inhibitors, integrase inhibitors, coreceptor specific agents, 3TC, AZT, nevirapine, non-nucleoside analogue reverse transcriptase inhibitors and nucleoside analogue reverse transcriptase inhibitors.

24. A diagnostic method comprising determining the sequence of an acquired
20 immunodeficiency virus envelope gene V3 region after initiating antiretroviral therapy to monitor efficacy of a antiretroviral treatment regimen and where efficacy of the treatment is directly related to decrease of CXCR4 coreceptor use.

25. The diagnostic method according to claim 24, wherein the envelope gene encodes gp160 or gp120.

25 26. The diagnostic method according to claim 24, wherein the acquired immunodeficiency virus is selected from the group consisting of HIV-1 and HIV-2.

27. The diagnostic method according to claim 24, wherein the antiretroviral therapy is selected from the group consisting of highly active antiretroviral therapy (HAART), protease inhibitors, fusion inhibitors, integrase inhibitors, coreceptor specific agents, 3TC, AZT, nevirapine, non-nucleoside analogue reverse transcriptase inhibitors and nucleoside analogue reverse transcriptase inhibitors.

28. The diagnostic method according to claim 20, wherein the sequence of the envelope gene V3 region is determined from a DNA micro-chip array.

29. The diagnostic method according to claim 24, wherein the sequence of the envelope gene V3 region is determined from a DNA micro-chip array.

30. A diagnostic method comprising determining CXCR4 coreceptor use, CCR5 coreceptor use, and a ratio of acquired immunodeficiency virus using the CXCR4 coreceptor compared to virus using the CCR5 coreceptor.

31. A diagnostic method comprising determining CXCR4 coreceptor use, CCR5 coreceptor use, and a ratio of acquired immunodeficiency virus using the CXCR4 coreceptor compared to virus using the CCR5 coreceptor before initiating antiretroviral therapy to determine a suitable antiretroviral treatment regimen.

32. A diagnostic method comprising determining CXCR4 coreceptor use, CCR5 coreceptor use, and a ratio of acquired immunodeficiency virus using the CXCR4 coreceptor compared to virus using the CCR5 coreceptor after initiating antiretroviral therapy to monitor efficacy of an antiretroviral treatment regimen and where efficacy of the treatment is directly related to decrease of CXCR4 coreceptor use.

33. A diagnostic method comprising transforming cells with an HIV envelope gene variant cloned from a patient infected with HIV, selectively fusing the cells with an indicator cell line expressing an HIV envelope-compatible coreceptor, and assaying for cell fusion before initiating antiretroviral therapy to determine a suitable antiretroviral treatment regimen.

34. The diagnostic method according to claim 33, wherein the acquired immunodeficiency virus is selected from the group consisting of HIV-1 and HIV-2.

35. The diagnostic method according to claim 33, wherein the antiretroviral therapy is selected from the group consisting of highly active antiretroviral therapy

5 (HAART), protease inhibitors, fusion inhibitors, integrase inhibitors, coreceptor specific agents, 3TC, AZT, nevirapine, non-nucleoside analogue reverse transcriptase inhibitors and nucleoside analogue reverse transcriptase inhibitors.

36. A diagnostic method comprising transforming cells containing a selectively activatable reporter gene construct with an HIV envelope gene variant cloned from

10 a patient infected with HIV, selectively fusing the cells with an indicator cell line containing a constitutively active transcriptional activator of the reporter gene construct and an HIV envelope-compatible coreceptor, and assaying for fusion by detection of reporter gene expression before initiating antiretroviral therapy to determine a suitable antiretroviral treatment regimen.

15 37. The diagnostic method according to claim 36, wherein the acquired immunodeficiency virus is selected from the group consisting of HIV-1 and HIV-2.

38. The diagnostic method according to claim 36, wherein the antiretroviral therapy is selected from the group consisting of highly active antiretroviral therapy (HAART), protease inhibitors, fusion inhibitors, integrase inhibitors, coreceptor

20 specific agents, 3TC, AZT, nevirapine, non-nucleoside analogue reverse transcriptase inhibitors and nucleoside analogue reverse transcriptase inhibitors.

39. A diagnostic method comprising transforming cells containing an HIV Tat-activatable reporter gene construct with an HIV envelope gene variant cloned from a patient infected with HIV, selectively fusing the cells with an indicator cell line

25 containing a constitutively active *tat* gene and an HIV envelope-compatible coreceptor, and assaying for fusion by detection of reporter gene expression before initiating antiretroviral therapy to determine a suitable antiretroviral treatment regimen.

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40. The diagnostic method according to claim 39 wherein the acquired immunodeficiency virus is selected from the group consisting of HIV-1 and HIV-2.

41. The diagnostic method according to claim 39, wherein the antiretroviral therapy is selected from the group consisting of highly active antiretroviral therapy (HAART), protease inhibitors, fusion inhibitors, integrase inhibitors, coreceptor specific agents, 3TC, AZT, nevirapine, non-nucleoside analogue reverse transcriptase inhibitors and nucleoside analogue reverse transcriptase inhibitors.

42. A diagnostic method comprising transforming cells with an HIV envelope gene variant cloned from a patient infected with HIV, selectively fusing the cells with an indicator cell line expressing an HIV envelope-compatible coreceptor, and assaying for cell fusion after initiating antiretroviral therapy to monitor efficacy of an antiretroviral treatment regimen and where efficacy of the treatment is directly related to decrease of CXCR4 coreceptor use.

43. The diagnostic method according to claim 42, wherein the acquired immunodeficiency virus is selected from the group consisting of HIV-1 and HIV-2.

44. The diagnostic method according to claim 42, wherein the antiretroviral therapy is selected from the group consisting of highly active antiretroviral therapy (HAART), protease inhibitors, fusion inhibitors, integrase inhibitors, coreceptor specific agents, 3TC, AZT, nevirapine, non-nucleoside analogue reverse transcriptase inhibitors and nucleoside analogue reverse transcriptase inhibitors.

45. A diagnostic method comprising transforming cells containing a selectively activatable reporter gene construct with an HIV envelope gene variant cloned from a patient infected with HIV, selectively fusing the cells with an indicator cell line containing a constitutively active transcriptional activator of the reporter gene construct and an HIV envelope-compatible coreceptor, and assaying for fusion by detection of reporter gene expression after initiating antiretroviral therapy to monitor efficacy of an antiretroviral treatment regimen and where efficacy of the treatment is directly related to decrease of CXCR4 coreceptor use.

46. The diagnostic method according to claim 45, wherein the acquired immunodeficiency virus is selected from the group consisting of HIV-1 and HIV-2.

47. The diagnostic method according to claim 45, wherein the antiretroviral therapy is selected from the group consisting of highly active antiretroviral therapy (HAART), protease inhibitors, fusion inhibitors, integrase inhibitors, coreceptor specific agents, 3TC, AZT, nevirapine, non-nucleoside analogue reverse transcriptase inhibitors and nucleoside analogue reverse transcriptase inhibitors.

48. A diagnostic method comprising transforming cells containing an HIV Tat-activatable reporter gene construct with an HIV envelope gene variant cloned from a patient infected with HIV, selectively fusing the cells with an indicator cell line containing a constitutively active *tat* gene and an HIV envelope-compatible coreceptor, and assaying for fusion by detection of reporter gene expression after initiating antiretroviral therapy to monitor efficacy of an antiretroviral treatment regimen and where efficacy of the treatment is directly related to decrease of CXCR4 coreceptor use.

49. The diagnostic method according to claim 54, wherein the acquired immunodeficiency virus is selected from the group consisting of HIV-1 and HIV-2.

50. The diagnostic method according to claim 54, wherein the antiretroviral therapy is selected from the group consisting of highly active antiretroviral therapy (HAART), protease inhibitors, fusion inhibitors, integrase inhibitors, coreceptor specific agents, 3TC, AZT, nevirapine, non-nucleoside analogue reverse transcriptase inhibitors and nucleoside analogue reverse transcriptase inhibitors.

51. A diagnostic composition comprising one or more cells comprising an HIV Tat-activatable reporter gene construct, an HIV envelope gene variant cloned from an infected patient, a constitutively active *tat* gene and an HIV envelope-compatible coreceptor.

52. The composition according to claim 51, wherein the coreceptor is CXCR4.

53.   The composition according to claim 51, wherein the coreceptor is CCR5.